



INCONTINENT CONTROL DEVICES, INC.

2727 Bens Branch Drive, Suite 1402, Kingwood, Texas 77339

MAY 27 2005

Ref: K042431

## 510(k) Summary

prepared: 09/30/04

Submitted by: Nyle Elliott  
Incontinent Control Devices, Inc.  
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Kingwood, Texas 77339  
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Contact person: Nyle Elliott

Trade name of device: Procon2  
Common name: Rectal Plug  
Classification: Gastrointestinal Tube & Accessories #876.5980

Incontinent Control Devices, Inc. is claiming equivalence of Procon2 to Procon, a class II Medical Device. K8642218 issued 01/12/1987

**Description of Procon2:** A single use rectal silicone catheter with a water filled cuff acting as a barrier to the unintended passage of feces through the rectum.

**Intended use for Procon2:** ProCon2 is a single use catheter with an inflatable balloon cuff intended to act as a barrier to the passage of fecal matter through the rectum. The device is intended for patients with significant fecal incontinence who are either not surgical candidates or have not responded to prior conservative and surgical treatment. The device is intended for self-insertion after a thorough demonstration of its use.

**Purposes and functions of Procon2:** 1. To provide a rectal barrier to the discharge of fecal matter. 2. To help prevent the spread of infectious diseases, and 3. To restore a better quality of life for the users.

**Technological characteristics of Predicate device:** ( Device number K8642218 issued 01/12/1987) A single use rectal balloon cuff, 16Fr Latex, Foley Catheter with a photo-sensor alarm, and an air-filled cuff acting as a barrier to the unintended passage of feces.

**Technological characteristics of Procon2:** A single use rectal balloon cuff, 18Fr. Silicone, Foley catheter (without a conventional electronic alarm) acting as a barrier to the unintended passage of feces.

**Technological characteristics of Procon2 compared to a legally marketed device which we are claiming equivalence:**

**Predicate Device:** Uses software  
**Procon2:** No software required

**Predicate Device:** Has low current circuitry using electrical conduit to a distal infrared sensor.  
**Procon2:** Has no electrical circuitry or sensor tip.

**Predicate Device:** Utilizes infrared photo-transducer to detect presence of fecal matter.  
**Procon 2:** Uses rectal tactile response or predetermined time to remind user when to evacuate.

**Predicate Device:** Uses a balloon cuff filled with 25cc of air  
**Procon2:** Uses a balloon cuff filled with 25cc of water.

**Predicate Device:** Provides a balloon barrier, sensor and alarm.  
**Procon2:** Provides a balloon barrier only.

**Predicate Device:** Catheter material is Latex  
**Procon2:** Catheter material is Silicone.

**Summary of Clinical Performance Data:**

Patient acceptance trials of the Predicate Device conducted at the Cleveland Clinic Florida, under the direction of the Chairman, Dept. of Colorectal Surgery, S.D. Wexner **M.D., F.A.C.S., F.R.C.S., F.R.C.S.Ed., F.A.S.C.R.S., F.A.C.G.**, determined the efficacy of the Predicate Device as a "mechanical barrier" to the impending passage of feces.

The medical text, Diagnosis and Treatment of Fecal Incontinence (2000) Giovanni Romano, P. a. Lehur, E. Weiss (eds). ISBN: 192864919X. Publisher: Idelson-Gnocchi Ltd. Publishing provides a summary of Dr. Wexner's findings:

"The ProCon Incontinence Device: A new Option for the Treatment of Symptoms of Fecal Incontinence" by Dr. Paolo Giamundo, S.D. Wexner states the following:

"The mechanical barrier component, however, cannot be underestimated even when patients voluntarily turned off the alarm, with the catheter still in position, very few experienced episodes of focal accidents or major leakage."



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 27 2005

Mr. Nyle Elliot  
Director of Product R & D  
Incontinent Control Devices, Inc.  
2727 Bens Branch Drive, Suite 1302  
KINGWOOD TX 77339

Re: K042431  
Trade/Device Name: Procon 2  
Regulation Number: 21 CFR §876.5980  
Regulation Name: Gastrointestinal tube and accessories  
Regulatory Class: II  
Product Code: KNT  
Dated: April 12, 2005  
Received: April 13, 2004

Dear Mr. Elliot:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

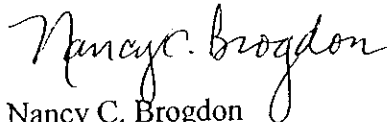
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

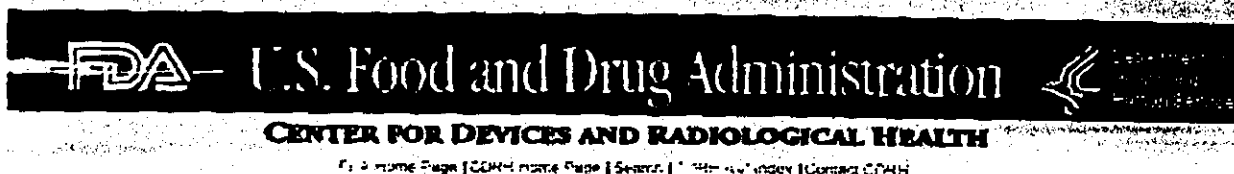
Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure



## Indications for Use

510(k) Number (if known): K042431

Device Name: Procon 2

Indications for Use:

Procon 2 is a single use catheter with an inflatable balloon cuff intended to act as a barrier to the passage of fecal matter through the rectum.

Procon2 is for an individual with fecal incontinence that has impaired quality of life, is sufficiently motivated psychologically to participate in their own treatment, and having good manual dexterity is an ideal candidate. He or she is either not a surgical candidate or has not responded to conservative treatment.

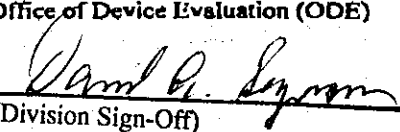
Prescription Use  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number

K042431

<http://www.fda.gov/cdrh/ode/INDICATE.HTML>

11/5/2004